510(k) Summary

JUL 2 0 2001

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Date: _____

Contact

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Submission Correspondent

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Device Name Blood Pressure Monitor Model HT-110

Common Name Blood Pressure Cuff

Classification The classification name, 21 CFR Part and Paragraph number, product code and classification of the Nissei Blood Pressure Monitor Model HT-110 follow. The tier categorization is also included.

Classification Name	21 CFR Section	Product Code	Class	Tier
Blood Pressure cuff	870.1120	DXQ	II	2
Stethoscope (Optional)	870.1875		I (exempt)	

Predicate Devices The Nissei Blood Pressure Monitor, Model HT-110 is substantially equivalent to following:

Device	Manufacturer	510(k) K#
Critikon	Johnson & Johnson	K974080
SoftCheck Cuff	Statcorp, Inc.	K940214

Device Description The device comprises tubing attached to a soft inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to a non-invasive sphygmomanometer.

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Indications	Device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.
Technological Characteristics	The Model HT-110 cuff is virtually the same as the Critikon adult devices. All of these devices are configured for use with a wide variety of manual and automated sphygmomanometers.
Performance	Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Model HT-110 cuff. Biocompatibility same as predicate devices. Repeated inflations and testing to ANSI/AAMI SP-9.
Conclusions	In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this premarket notification, Nihon Seimitsu Sokki Co., Ltd., concludes that the Model HT-110 Blood Pressure Cuff, is safe and effective and substantially equivalent to the predicate devices as described herein.
Other	Nihon Seimitsu Sokki Co., Ltd., will update and include in this summary any other information deemed reasonably necessary by the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2001

Nihon Seimitsu Sokki Co., Ltd.
c/o Mr. Mark Job
TÜV Product Service, Inc.
1775 Old Highway 8 NW, Suite 104
New Brighton, MN 55112-1891

Re: K012194
Trade Name: Blood Pressure Monitor (Sphygmomanometer), Model HT-110
Regulation Number: 21 CFR 870.1120
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: July 12, 2001
Received: July 13, 2001

Dear Mr. Job:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish

further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 012194

Device Name: Blood Pressure Monitor Model Ht-110

Indications for use:

Device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K012194

Prescription Use _____ OR Over-The-Counter Use Yes

(Per 21 CFR 801.109)

(Optional Format 1-2-96)